

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

<p>PHILIP BARGE,</p> <p>Plaintiffs,</p> <p>vs.</p> <p>BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS U.S. L.L.C., SANOFI- AVENTIS U.S., INC., SANOFI- SYNTHELABO, INC.,</p> <p>Defendants.</p>	<p>Civil Action No: 3:07-cv-00783 (FLW-TJB)</p> <p><b>BRIEF IN SUPPORT OF MOTION TO DISMISS PURSUANT TO <u>R.</u> 12(b)(6)</b></p>
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**BRIEF IN SUPPORT OF MOTION TO DISMISS PURSUANT TO R. 12(b)(6)**

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### **PRELIMINARY STATEMENT**

Plaintiff Philip Barge, without any factual basis, asserts boilerplate, meritless fraud claims against Defendants. These claims, supported by nothing more than vague and conclusory allegations, should be dismissed for failing to state a claim upon which relief can be granted.

Plaintiff Philip Barge, a Georgia resident, filed an Amended Complaint in the United States District Court for the District of New Jersey seeking damages for personal injuries and economic loss allegedly associated with his use of Plavix®. Plaintiff's Amended Complaint asserts a variety of claims based on the Georgia Fair Business Practices Act, O.G.C.A. §10-1-392 et seq. ("GFBPA" or the "Act") and Georgia common law. Plaintiff's GFBPA claims, however, fail to satisfy the pleading requirements of Federal Rules of Civil Procedure 12(b)(6). While a complaint does not need to assert detailed factual allegations, it must provide more than mere labels and conclusions to withstand the scrutiny required by Rule 12(b)(6). Plaintiff has not met this burden.

Defendants Sanofi-Aventis U.S., LLC, Sanofi-Aventis U.S., Inc., Sanofi-Synthelabo, Inc. and Bristol-Myers Squibb Company submit this brief in support of Defendants' motion to dismiss Plaintiff's GFBPA claims because, quite simply, these claims, as pled, are not legally cognizable as a matter of law.

### **STATEMENT OF FACTS**

Plavix® (clopidogrel bisulfate) was first approved for sale in the United States by the U.S. Food and Drug Administration ("FDA") in November 1997, for the reduction of atherosclerotic events (myocardial infarction, stroke, and vascular death) in patients who had recently suffered a stroke or myocardial infarction, or who had established peripheral arterial disease. (See FDA Approval Letter dated November 17, 1997<sup>1</sup> attached as Exhibit A). As the demonstrated clinical

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<sup>1</sup> Though some of the facts provided herein are not specifically set forth in the Complaint, the information has been referred to by Plaintiff and is integral to the Court's understanding of the

benefit of Plavix® expanded, the FDA approved additional indications for it and Plavix® has become the gold standard for treatment of atherothrombotic events. As a result, Plavix® is one of the most prescribed medications on the market today - providing a critical medical benefit to millions of patients around the world each year.

Plaintiff alleges that he began “dual therapy” of Plavix® and aspirin in or around October 2003 in connection with a stent placements for mild atherosclerotic disease and that on or about February 16, 2005 he went to the hospital with flu-like symptoms and was diagnosed with a “bleeding ulcer”. (See Plaintiff’s First Amended Complaint ¶ 31 – hereinafter “Complaint” – attached as Exhibit B). Plaintiff further alleges that had Defendants provided “adequate warnings regarding the risks of Plavix, he would not have used it.” (Complaint ¶ 60). Plaintiff now seeks damages under a variety of legal theories under Georgia law including fraud under the GFBPA.

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documents and terms relied upon by Plaintiff’s counsel. As recognized by this Court in Adamson v. Ortho-McNeil Pharmaceutical Inc., 2006 WL 3333390 at \*3 (D.N.J. November 16, 2006) (relying upon, In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1426 (D.N.J. 1997)), documents expressly relied upon or integral to the complaint and matters of public record, if the claims of the plaintiff are based upon such documents, may be considered. The failure of a plaintiff to attach or cite documents in the complaint does not preclude a court from reviewing extrinsic documents. Id. The rationale underlying this exception [to the normal rule] is that the primary problem raised by looking to documents outside the complaint, i.e. lack of notice to the plaintiff, is dissipated “[w]here plaintiff has actual notice . . . and has relied upon these documents in framing the complaint. Id.

## LEGAL ARGUMENT

### **I. PLAINTIFF'S CLAIM UNDER THE GEORGIA FAIR BUSINESS PRACTICES ACT SHOULD BE DISMISSED PURSUANT TO FED. R. CIV. P. 12(b)(6).**

Pursuant to Federal Rule of Civil Procedure 12(b)(6), a court may dismiss all or part of an action by motion, prior to the filing of a responsive pleading, for a "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). For a complaint to withstand a motion to dismiss under Fed. R. Civ. P. 12(b)(6), the factual allegations set forth in a complaint "must be enough to raise a right to relief above the speculative level." Rosamilia v. ACB Receivables Mgmt., 2009 U.S. Dist. LEXIS 33684, 3-5 (D.N.J. Apr. 22, 2009), citing Bell Atl. Corp. v. Twombly, 550 U.S. 444, 555-56 (2007), see also, Bernegger v. Washington Mutual 2008 U.S. Dist. LEXIS 19291, at \*4 (E.D. Wis. Feb. 29, 2008) citing Fed. R. Civ. P. 12(b)(6) (motion to dismiss granted in part as to fraudulent misrepresentation and negligent misrepresentations claims). While a complaint does not need to assert detailed factual allegations, a plaintiff's obligation to provide the grounds of his or her entitlement to relief "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Phillips v. County of Allegheny, 515 F.3d 224, 231 (3d Cir. 2008), citing Bell Atlantic Corp. v. Twombly, 550 U.S. at 554.

Plaintiff's GFBPA claims fails to state a claim upon which relief can be granted for three reasons. First, the GFBPA specifically exempts the Defendants alleged acts from liability as the Act itself states that it does not apply to actions specifically authorized by any federal regulatory body or agency. See O.G.C.A. § 10-1-396(1). Second, Plaintiff attempts to plead his cause of action under the GFBPA, O.G.C.A., 10-1-390 et seq. by simply re-stating each of the required elements under the GFBPA in a conclusory fashion. Allegations of this sort, however, are not sufficient to support a viable legal claim under the GFBPA. Third, Plaintiff failed to provide notice of the claim prior to

the commencement of the action as required under the GFBPA. See O.G.C.A. § 10-1-399(b). For these reasons, Plaintiff's claims under the GFBPA should be dismissed.

**A. As a Matter of Law, Plaintiff's Claim under the GFBPA fails due to Exemption by Statutory Provision O.G.C.A. § 10-1-396(1).**

Plaintiff's consumer fraud claim fails under the GFBPA because the Defendants are *statutorily* exempted from liability. The GFBPA specifically exempts a defendant from liability when its "actions or transactions [are] specifically authorized by laws administered by any regulatory body or officer acting under statutory authority of this State or the United States." O.G.C.A. § 10-1-396(1). This exemption was created by the Georgia General Assembly which intended that "the [GFBPA] have a restricted application only to the unregulated consumer marketplace and that [G]FBPA not apply in regulated areas of activity, because regulatory agencies provide protection or the ability to protect against the known evils in the area of the agency's expertise." Chancellor v. Gateway Lincoln-Mercury, Inc., 233 Ga. App. 38, 45 (Ga. Ct. App. 198). The "reported cases, both in Georgia and the federal courts applying the Georgia statute, have construed the exemption to cover conduct that is regulated, unless the [G]FBPA or another statute provides otherwise." In Re: Bobby Joe Taylor, Jr. v. Steven Jacques D/B/A In-house Mortgage, 2002 Bankr. LEXIS 1689, at \*10-11 (N. Dist. GA January 29, 2002). The pharmaceutical industry is an industry that is highly regulated, both at the federal level and international levels. Bober v. Glaxo Wellcome Plc, 246 F.3d 934, 942 (7th Cir. 2001).

Here, all of the statements allegedly made by Defendants regarding Plavix® fall under O.G.C.A. § 10-1-396(1) and are exempted for two reasons. First, any action or transaction involving Plavix® would be authorized or administered by FDA. Plavix® was approved in November 1997 by FDA for the indications discussed *supra* and any advertisements in relation to the marketing of the medicine would have also been authorized by FDA. Second, Plaintiff specifically concedes that



Plavix® was reviewed by FDA so it could be brought to the market in November 1997. (Complaint ¶12). Thus, FDA authorization is undisputed in this case. Accordingly, Plaintiff's allegations relating to the GFBPA should be dismissed as the GFBPA specifically exempts Defendants from liability.

**B. As a Matter of Law, Plaintiff's Claim under the GFBPA Fails Pursuant to Rule 12(b)(6).**

Plaintiff fails to state a claim under the GFBPA, O.G.C.A. §10-1-392 et seq. Three elements are required under the GFBPA, (1) violation of the Act; (2) causation; and (3) injury. See Johnson v. GAPVT Motors, Inc., 292 Ga. App. 79, 84 (Ga. Ct. App. 2008). The required causation element is only adequately pled if the claimant demonstrates that he was injured *as a result* of the reliance upon the alleged misrepresentation. Tiismann v. Linda Martin Homes Corp., 281 Ga. 137, 138 (Ga. 2006)(emphasis added). Therefore, in order for a Defendant to be subject to liability under the GFBPA, the Plaintiff's injury, must have been caused by the Defendant's act which was in violation of the GFBPA. Id.

Here, Plaintiff fails to meet his burden. Not only does Plaintiff's Amended Complaint fail to identify the "untrue, deceptive or misleading advertisements" that were allegedly made, but it also fails to allege that Plaintiff heard or relied upon these statements in filling his prescription for Plavix®. Accordingly, Plaintiff's GFBPA claim should be dismissed for failing to state a claim upon which relief can be granted because Plaintiff failed to adequately plead reliance.

Plaintiff has also failed to properly plead his damage claim under the GFBPA. Though actual damages are recoverable under the GFBPA, they are limited to the **actual injury suffered**. Regency Nissan v. Taylor, 194 Ga. App. 645, 649 (Ga. Ct. App. 1990)(internal citations omitted)(emphasis added). The damage claims asserted in Plaintiff's Complaint go well beyond those permitted by the GFBPA. Plaintiff seeks actual and punitive damages, including damages for

loss of earning capacity. Plaintiff's damage claim also fails to follow the specific remedies available under the GFBPA and the Complaint fails to allege the facts necessary to make that calculation or to ascertain the pecuniary loss. Accordingly, Plaintiff has also failed to properly plead his claim for damages under the GFBPA.

**C. As a Matter of Law, Plaintiff's Claim under the GFBPA must be Dismissed Due Failure to Provide Notice Pursuant to O.G.C.A. § 10-01-399(b).**

Plaintiff's GFBPA claim must also be dismissed for his failure to comply with the notice requirements set forth in O.G.C.A. § 10-01-399(b). The GFBPA was designed to provide various protections to consumers of goods and services. The GFBPA is not, however, without its own limitations. Prior to the commencement of an action seeking damages pursuant to the GFBPA, a plaintiff must provide the defendant with notice of the particular alleged violations of the GFBPA, O.G.C.A. § 10-1-392 et seq., O.G.C.A. § 10-1-399 (b). In pertinent part, O.G.C.A. § 10-1-399(b) of the Georgia Code Annotated provides that:

At least thirty days prior to the filing of any such action, a written demand for relief, identifying the claimant and reasonably describing the unfair or deceptive actor or practice relied upon and the injury suffered, shall be delivered to any prospective respondent...

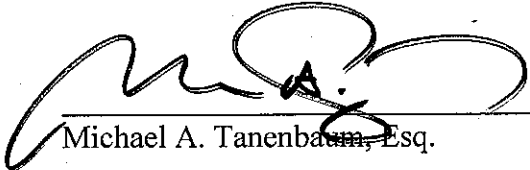
The purpose of this notice requirement is "to reduce the need for litigation by giving the prospective respondent the opportunity to resolve the claim before suit is filed." SunTrust Bank v. Hightower, 291 Ga. App. 62, 65 (Ga. Ct. App. 2008). Georgia courts have held that the notice is sufficient if it apprises the recipient "of the underlying facts giving rise to" the sender's claim; it need not cite the appropriate Code section. Stringer v. Bugg, 254 Ga. App. 745, 747 (Ga. Ct. App. 2002) citing Colonial Lincoln-Mercury v. Molina, 152 Ga. App. 379, 383 (1979). Plaintiff has failed to comply with this notice requirement.

Plaintiff's Amended Complaint asserts a cause of action based on violations of the GFBPA which, by statute, requires thirty days notice to the respondent. See Complaint ¶¶ 72-89; see also O.G.C.A. § 10-1-399(b). Despite filing a claim pursuant to O.G.C.A. § 10-1-392 et seq. of the GFBPA, plaintiff failed to provide the requisite notice required O.C.G.A. § 10-1-399(b). Accordingly, plaintiff's claim for damages under the GFBPA should be dismissed pursuant to Fed. R. Civ. P. 12(b)(6). See White v. Wachovia Bank, N.A., 563 F. Supp. 2d 1358, 1363 (N.D. Ga. 2008) (court "assumed" that if not raised on a motion to dismiss the notice/demand requirement under O.G.C.A. § 10-1-399(b) is met).

### **CONCLUSION**

In light of the foregoing, it is respectfully requested that this Court dismiss Plaintiff's GFBPA claims for failing to state claims upon which relief can be granted. This claim, as pled in Plaintiff's Amended Complaint, fails as a matter of law pursuant to Federal Rule of Civil Procedure 12(b)(6) and therefore should be dismissed.

Respectfully submitted,



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